POLICY: Oncology (Other) – Anktiva Utilization Management Medical Policy
- Anktiva® (nogapendekin alfa inbakicept-pmln intravesical solution – ImmunityBio)

EFFECTIVE DATE: 08/15/2024
LAST REVIEW DATE: 04/30/2025

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Anktiva, an interleukin-15 (IL-15) receptor agonist, is indicated with Bacillus Calmette-Guerin (BCG) for the treatment of **BCG-unresponsive non-muscle invasive bladder cancer** (NMIBC) in adults with carcinoma in situ with or without papillary tumors.[1]

Dosing Information

Anktiva is for intravesical use only.[1] For induction therapy, the recommended dose is 400 mcg administered intravesically with BCG once weekly for 6 weeks. A second induction course can be administered if the patient did not achieve a complete response at month 3. For maintenance therapy, the recommended dose is 400 mcg with BCG once weekly for 3 weeks at months 4, 7, 10, 13, and 19. For patients with an ongoing complete response at month 25, additional doses of 400 mcg plus BCG can be given once weekly for 3 weeks at months 25, 31, and 37. Treatment can continue until disease persistence after the second course of induction therapy, disease recurrence or progression, unacceptable adverse events, or a maximum of 37 months.

Guidelines

The National Comprehensive Cancer Network (NCCN) **bladder cancer** clinical guidelines (version 1 .2025 – March 25, 2025) recommend Anktiva for the treatment of BCG-unresponsive, high-risk NMIBC with CIS with or without papillary tumors (category 2A) as initial treatment or for cytology-positive, imaging- and cystoscopy-negative, recurrent or persistent disease.[3,4]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Anktiva. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is

equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Anktiva as well as the monitoring required for adverse events and long-term efficacy, approval requires Anktiva to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Anktiva is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. Non-Muscle Invasive Bladder Cancer. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy: Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

Note: This allows enough time for a patient to complete two courses of induction therapy if needed.

- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient has high risk Bacillus Calmette-Guerin (BCG) unresponsive disease; AND
- **iii.** Patient has carcinoma in situ (CIS); AND
- **iv.** Medication is used in combination with BCG; AND
- **v.** Medication is prescribed by or in consultation with a urologist or an oncologist; OR

B) Maintenance Therapy: Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):

- **i.** Patient has an ongoing compete response defined as ONE of the following (a or b):
  - **a)** Patient has negative cystoscopy and meets ONE of the following [(1) or (2)]:
    - **(1)** Negative urine cytology; OR
    - **(2)** Malignant urine cytology if cancer found in the upper tract or prostatic urethra and random bladder biopsies are negative; OR
  - **b)** Patient has positive cystoscopy with biopsy-proven benign or low-grade Ta non-muscle invasive bladder cancer and negative urine cytology; AND
- **ii.** Medication is used in combination with BCG; AND
- **iii.** Medication is prescribed by or in consultation with a urologist or an oncologist.

Dosing. Approve the following dosing regimens (A or B):

A) Induction Therapy: Approve 400 mcg administered intravesically once a week for 6 weeks. A second course of induction therapy can be administered at month 3 if a complete response was not achieved with the first course; OR

B) Maintenance Therapy: Approve 400 mcg administered intravesically once a week for 3 weeks at months 4, 7, 10, 13, and 19. Additional course can be given at months 25, 31, and 37.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Anktiva is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Anktiva intravesical solution [prescribing information]. Culver City, CA: ImmunityBio; April 2024.
2. Chamie K, Chang SS, Kramolowsky E, et al. IL-15 superagonist NAI in BCG-unresponsive non-muscle-invasive bladder cancer. *NEJM Evid*. 2023;2(1):EVIDoa2200167.
3. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – March 25, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 9, 2025.
4. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Search term: nogapendekin. Accessed on April 9, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/08/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Update	04/04/2025: The policy name was changed from "Oncology (Other) - Anktiva UM Medical Policy" to "Oncology (Intravesical) - Anktiva UM Medical Policy".	NA
Annual Revision	**Non-Muscle Invasive Bladder Cancer:** For the requirement that the patient has Bacillus Calmette-Guerin (BCG) unresponsive disease, added "high-risk" as a qualifier. For the requirement that the patient has carcinoma in situ, removed "with or without papillary tumors".	04/30/2025